



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/824,298

04/14/2004

Haimanot Bekele

9211M

6061

27752 7590 05/12/2009
THE PROCTER & GAMBLE COMPANY
Global Legal Department - IP
Sycamore Building - 4th Floor
299 East Sixth Street
CINCINNATI, OH 45202

EXAMINER

PAGONAKIS, ANNA

ART UNIT

PAPER NUMBER

1614

MAIL DATE

DELIVERY MODE

05/12/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/824,298 | Applicant(s) BEKELE ET AL. | |
| | Examiner ANNA PAGONAKIS | Art Unit 1614 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/3/2008 & 2/24/2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 16-24 is/are pending in the application.
- 4a) Of the above claim(s) 18 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 16-17 and 20-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1 sheet, 10/3/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-11, 16-17 and 20-24 are presented for examination.

In the reply filed on 2/24/2009, Applicant re-elected the co-polymer poly-2-hydroxy-ethyl methacrylate-co-4-hydroxybutyl acrylate.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 CFR 1.114. Applicant's payment and submission filed 12/23/2008, has been received and entered into the present application. Accordingly, prosecution has been reopened.

Claims 1-11 and 16-24 are pending and under examination. Claim 1, 16-19 is amended and claims 12-15 have been cancelled. Claims 18-19 remain withdrawn for being drawn to non-elected subject matter

Applicant's arguments, filed 10/3/2008 & 2/24/2009 have been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections being applied to the instant application.

Objection

Claim 18 is objected to because of the following informalities: the word "glycerol" is misspelled. The correct spelling is glycerol. Appropriate correction is required.

Art Unit: 1614

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11, 16-17 and 20-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term “from about,” “at least about” and “less than about” are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, one of ordinary skill in the art would be reasonably apprised of the scope of the invention, because one of skill will not be able to determine which term is in control. The claims lack clarity as to whether "from" (a lower limit) or "about" (broadening limitation, both higher and lower) controls the metes and bounds of the phrase "from about." Regarding "at least" (a lower limit) or "about" (broadening limitation, both higher and lower) it is unclear what controls the metes and bounds of the phrase “at least about.” Regarding "less than (a lower limit) or "about" (broadening limitation, both higher and lower) it is unclear what controls the metes and bounds of the phrase "less than about." Further, in claims 1, 16-17 what does about 1 mean ?... how can one skilled in the art envision less than one. Is the intent to encompass fragments of the base polymer structure where any of m, n, and y are =O (i.e. absent)?

Claims 1-3 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "at a level" in claim 1-3 and 5 renders the claim indefinite. Is this a weight percent ? and what is the percent relative to, the composition ? The phrase is not defined by the claim, the

Art Unit: 1614

specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not reasonably be apprised of the scope of the invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5, 8-9, 11 and 20 are rejected under 35 U.S.C. 102(b) as being unpatentable over Holguin et al. (U.S. 2001/0037006 A1) in light of MeSH Supplementary Data, 2009 and Glyceryl Ether (www.wrongdiagnosis.com, 2009).

Holguin et al. provides a method for the preparation of a copolymer of 2-hydroxyethyl methacrylate and 4-hydroxybutyl acrylate containing ethylene glycol and a solution of water and alcohol (abstract). The copolymers of 2-hydroxyethyl methacrylate and 4-hydroxybutyl acrylate can be utilized as a topical skin coating or barrier. The copolymer may also be a component of a cream, including water in oil emulsions and oil in water emulsions, lotions, which are suspensions in water and oil, ointments or aerosols (paragraph [0050]). The co-polymer can be self cross-linking by heat treating at a temperature in the range of about 70 degrees Celsius to about 150 degrees Celsius (paragraph [0053]). The cosmetic composition comprising the copolymer of 2-hydroxyethyl methacrylate and 4-hydroxybutyl acrylate is easy to apply and to remove from the surface of human skin, it is non-greasy and non-occlusive (paragraph [0056]). The copolymer of 2-hydroxyethyl methacrylate and 4-hydroxybutyl acrylate can be blended with a polyalkylene glycol or polyethylene glycol (paragraph [0058]). The glass transition temperature can be 5 degrees Celsius. The composition can have a viscosity of 844 cPs or 39,000 cPs

Art Unit: 1614

(paragraphs [0129] and [0150]). Glycerin can be used as a pharmacological active agent (paragraph [0091]).

MeSH Supplementary Data teaches that glycerin is an alternative name for glycerol.

Glyceryl ether (www.wrongdiagnosis.com) teaches that glyceryl ether is an alternative term for glycerol).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-11, 20 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holguin et al. (U.S. 2001/0037006 A1) in view of Kaleta et al. (U.S. 5,618,522) in light of MeSH Supplementary Data, 2009 and Glyceryl Ether (www.wrongdiagnosis.com, 2009).

Holguin et al. provides a method for the preparation of a copolymer of 2-hydroxyethyl methacrylate and 4-hydroxybutyl acrylate containing ethylene glycol and a solution of water and alcohol (abstract). The copolymers of 2-hydroxyethyl methacrylate and 4-hydroxybutyl acrylate can be utilized

Art Unit: 1614

as a topical skin coating or barrier. The copolymer may also be a component of a cream, including water in oil emulsions and oil in water emulsions, lotions, which are suspensions in water and oil, ointments or aerosols (paragraph [0050]). The co-polymer can be self cross-linking by heat treating at a temperature in the range of about 70 degrees Celsius to about 150 degrees Celsius (paragraph [0053]). The cosmetic composition comprising the copolymer of 2-hydroxyethyl methacrylate and 4-hydroxybutyl acrylate is easy to apply and to remove from the surface of human skin, it is non-greasy and non-occlusive (paragraph [0056]). The copolymer of 2-hydroxyethyl methacrylate and 4-hydroxybutyl acrylate can be blended with a polyalkylene glycol or polyethylene glycol (paragraph [0058]). The glass transition temperature can be 5 degrees Celsius. The composition can have a viscosity of 844 cPs or 39,000 cPs (paragraphs [0129] and [0150]). Glycerin can be used as a pharmacological active agent (paragraph [0091]). Further it is taught that gels can be used in the composition in order to create a sprayable solution (paragraph [0050]).

Holguin does not teach the addition of cationic polyacrylate.

MeSH Supplementary Data teaches that glycerin is an alternative name for glycerol.

Kaletka et al. teach that cationic polyacrylate polymers are useful as thickeners and gelling agents (column 13).

Glyceryl ether (www.wrongdiagnosis.com) teaches that glyceryl ether is an alternative term for glycerol.

Thus, it would have been *prima facie* obvious to including a gelling agent such as cationic polyacrylate in the composition of Holguin et al. One would be motivated to do since a sprayable solution of the composition can be achieved with the use of gels and further cationic polyacrylate is known to be a gel.

The percentage of specific components present in the composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters

Art Unit: 1614

is a routine practice that would be obvious for a person of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention.

Claim 21 is are rejected under 35 U.S.C. 103(a) as being unpatentable over Holguin et al. (U.S. 2001/0037006 A1) in view of Kaleta et al. (U.S. 5,618,522) in light of MeSH Supplementary Data, 2009 and Glyceryl Ether (www.wrongdiagnosis.com, 2009), as applied to claim 16 above, and further in view of Kamen et al. (U.S. 5,066,486).

The combination of Holguin et al. (U.S. 2001/0037006 A1) in view of Kaleta et al. (U.S. 5,618,522) in light of MeSH Supplementary Data, 2009 and Glyceryl Ether (www.wrongdiagnosis.com, 2009) is set forth *supra*. The combination differs by not teaching a pigment.

Kamen et al. teaches the use of pigment components in the preparation of lipstick products which are widely utilized for coloration in cosmetic products. Among these are barium lake, titanium dioxide and ferric oxide (column 5).

It would have been *prima facie* obvious to the skilled artisan at the time the invention was made to add pigments such as barium lake, titanium dioxide and ferric oxide to the composition. One would be motivated to do so because the lip composition are known to have pigments added to them in order to provide desired coloration.

Art Unit: 1614

Claims 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Holguin et al. (U.S. 2001/0037006 A1) in light of MeSH Supplementary Data, 2009 and Glyceryl Ether (www.wrongdiagnosis.com, 2009).

Holguin et al. provides a method for the preparation of a copolymer of 2-hydroxyethyl methacrylate and 4-hydroxybutyl acrylate containing ethylene glycol and a solution of water and alcohol (abstract). The copolymers of 2-hydroxyethyl methacrylate and 4-hydroxybutyl acrylate can be utilized as a topical skin coating or barrier. The copolymer may also be a component of a cream, including water in oil emulsions and oil in water emulsions, lotions, which are suspensions in water and oil, ointments or aerosols (paragraph [0050]). The co-polymer can be self cross-linking by heat treating at a temperature in the range of about 70 degrees Celsius to about 150 degrees Celsius (paragraph [0053]). The cosmetic composition comprising the copolymer of 2-hydroxyethyl methacrylate and 4-hydroxybutyl acrylate is easy to apply and to remove from the surface of human skin, it is non-greasy and non-occlusive (paragraph [0056]). The copolymer of 2-hydroxyethyl methacrylate and 4-hydroxybutyl acrylate can be blended with a polyalkylene glycol or polyethylene glycol (paragraph [0058]). The glass transition temperature can be 5 degrees Celsius. The composition can have a viscosity of 844 cPs or 39,000 cPs (paragraphs [0129] and [0150]). Glycerin can be used as a pharmacological active agent (paragraph [0091]). Further it is taught that gels can be used in the composition in order to create a sprayable solution (paragraph [0050]). Additional pharmacological active agents included can be castor oil, mineral oil, petroleum cetyl palmitate, cetyl alcohol and stearyl alcohol (paragraph [0091]).

Holguin et al. does not teach a kit of the composition.

MeSH Supplementary Data teaches that glycerin is an alternative name for glycerol.

Glyceryl ether (www.wrongdiagnosis.com) teaches that glyceryl ether is an alternative term for glycerol.

Art Unit: 1614

It would have been *prima facie* obvious to include kit instructions or list of items in with the kit composition, such that one is informed of the usage, storage protocol and administration regimens. Please note, with respect of the printed matter on a label or package insert does not lend patentable weight as a limitation of the claimed product, composition, or article of manufacture, absent a functional relationship between the label or package insert and the product, composition, or article of manufacture. See In re Haller 73 USPQ 403 (CCPA 1947), where it is held that application of printed matter to old article cannot render the article patentable. In the opinion text of In re Haller, it is stated that: Whether the statement of intended use appears merely in the claim or in a label on the product is immaterial so far as the question of patentability is concerned...In accordance with the patent statutes, an article or composition of matter, in order to patentable, must not only be useful and involve invention, but must also be *new*. If there is no novelty in an article or composition itself, then a patent cannot be properly granted on the article or composition, regardless of the use for which it is intended. The difficulty is not that there can never be invention in discovering a new process involving the use of an old article, but that the statutes make no provision for patenting of an article or composition which is not, in and of itself, new. Also see In re Venezia 189 USPQ 49 (CCPA 1976), where kits are drawn to the structural attributes of interrelated component parts and not to activities that may or may not occur. Further, In re Miller 164 USPQ 46 (CCPA 1969) and In re Gulak (CA FC)217 USPQ 401 relate to a mathematical device and to a measuring cup respectively. In each of these cases, the printed matter is considered a patentable distinction because the function of the device depends upon the printed matter itself which is a part of the substrate; without the printed indicia or numbers, the substrates lose their function. Such is not the case with the instantly claimed articles. The proteins of the claimed articles remain fully functional absent the labeling or printed instructions for use. It is further noted that the written material in the instructions is not considered to be within the statutory classes and does not carry patentable weight. See MPEP 706.03(a). Thus the instructions for use included in a kit or article manufacture constitute an “intended use” for that

Art Unit: 1614

kit or article of manufacture. Intended use does not impart patentable weight to a product. See MPEP 2111.03 Intended use recitations and other types of functional language cannot be entirely disregarded. However, in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); *In re Otto*, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963). The intended use which is recited on the label or package insert lacks a function relationship to the compound because the insert or label does not physically or chemically affect the chemical nature of the compound within the article of manufacture, and furthermore, the compound can still be used by the skilled artisan for other purposes. Therefore the compounds which are comprised within the article of manufacture are unpatentable over the prior art composition as combined, because they function equally effectively with or without the instructions, and accordingly no functional relationship exists between the instructions for use and the claimed composition. Thus the claims are addressed as being drawn to an article of manufacture comprising a chemical composition and a kit, the kit on the insert bearing no patentable weight.

Claim 23 is are rejected under 35 U.S.C. 103(a) as being unpatentable over Holguin et al. (U.S. 2001/0037006 A1)) in light of MeSH Supplementary Data, 2009 and Glyceryl Ether (www.wrongdiagnosis.com, 2009), as applied to claim 16 above, and further in view of Claverie et al (U.S. 6,706,877).

The combination of Holguin et al. (U.S. 2001/0037006 A1) in light of MeSH Supplementary Data, 2009 and Glyceryl Ether (www.wrongdiagnosis.com, 2009) is set forth *supra*. The combination differs by not teaching sucrose polyester.

Art Unit: 1614

Claverie et al. teaches that sucrose polyester is an emulsifier.

It would have been *prima facie* obvious to the skilled artisan at the time the invention was made to add sucrose polyester to the composition. One would be motivated to do so because the composition taught by Holguin et al. teaches the composition as an emulsion, and sucrose polyester as an emulsifier would assist in formation of an emulsion.

Claims 17 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holguin et al. (U.S. 2001/0037006 A1) in view of Morita et al. (U.S. 6,500,439) in light of MeSH Supplementary Data, 2009 and Glyceryl Ether (www.wrongdiagnosis.com, 2009).

Holguin et al. provides a method for the preparation of a copolymer of 2-hydroxyethyl methacrylate and 4-hydroxybutyl acrylate containing ethylene glycol and a solution of water and alcohol (abstract). The copolymers of 2-hydroxyethyl methacrylate and 4-hydroxybutyl acrylate can be utilized as a topical skin coating or barrier. The copolymer may also be a component of a cream, including water in oil emulsions and oil in water emulsions, lotions, which are suspensions in water and oil, ointments or aerosols (paragraph [0050]). The co-polymer can be self cross-linking by heat treating at a temperature in the range of about 70 degrees Celsius to about 150 degrees Celsius (paragraph [0053]). The cosmetic composition comprising the copolymer of 2-hydroxyethyl methacrylate and 4-hydroxybutyl acrylate is easy to apply and to remove from the surface of human skin, it is non-greasy and non-occlusive (paragraph [0056]). The copolymer of 2-hydroxyethyl methacrylate and 4-hydroxybutyl acrylate can be blended with a polyalkylene glycol or polyethylene glycol (paragraph [0058]). The glass transition temperature can be 5 degrees Celsius. The composition can have a viscosity of 844 cPs or 39,000 cPs (paragraphs [0129] and [0150]). Glycerin can be used as a pharmacological active agent (paragraph [0091]). Further it is taught that gels can be used in the composition in order to create a sprayable

Art Unit: 1614

solution (paragraph [0050]). Additional pharmacological active agents included can be castor oil, mineral oil, petroleum cetyl palmitate, cetyl alcohol and stearyl alcohol (paragraph [0091]).

Holguin et al. does not teach the addition of silicone modified fluorinated polymers.

MeSH Supplementary Data teaches that glycerin is an alternative name for glycerol.

Glyceryl ether (www.wrongdiagnosis.com) teaches that glyceryl ether is an alternative term for glycerol.

Morita et al. discloses copolymers used in cosmetic compositions as thickeners. The copolymers comprise a fluorine-containing (meth)acrylate and a silicone macromonomer. The copolymer is used with a hydrocarbon based solvent or a silicone based solvent, including isododecane (column 10, lines 32-35).

It would be within the knowledge of one of ordinary skill to add silicone modified fluorinated polymers in the composition taught by Holguin et al. One would be motivated to do so since Morita discloses that fluorine modified copolymer is to be used in a cosmetic composition in order to form a film excellent in water resistance and as a thickener. It would have been obvious to incorporate the polymers into the complimentary product to achieve the desired effects of the polymers.

It would have been *prima facie* obvious to include kit instructions or list of items in with the kit composition, such that one is informed of the usage, storage protocol and administration regimens. Please note ,with respect of the printed matter on a label or package insert does not lend patentable weight as a limitation of the claimed product, composition, or article of manufacture, absent a functional relationship between the label or package insert and the product, composition, or article of manufacture. See In re Haller 73 USPQ 403 (CCPA 1947), where it is held that application of printed matter to old article cannot render the article patentable. In the opinion text of In re Haller, it is stated that: Whether the statement of intended use appears merely in the claim or in a label on the product is immaterial so far as the question of patentability is concerned...In accordance with the patent statutes, an article or

Art Unit: 1614

composition of matter, in order to patentable, must not only be useful and involve invention, but must also be *new*. If there is no novelty in an article or composition itself, then a patent cannot be properly granted on the article or composition, regardless of the use for which it is intended. The difficulty is not that there can never be invention in discovering a new process involving the use of an old article, but that the statutes make no provision for patenting of an article or composition which is not, in and of itself, new. Also see In re Venezia 189 USPQ 49 (CCPA 1976), where kits are drawn to the structural attributes of interrelated component parts and not to activities that may or may not occur. Further, In re Miller 164 USPQ 46 (CCPA 1969) and In re Gulak (CA FC) 217 USPQ 401 relate to a mathematical device and to a measuring cup respectively. In each of these cases, the printed matter is considered a patentable distinction because the function of the device depends upon the printed matter itself which is a part of the substrate; without the printed indicia or numbers, the substrates lose their function. Such is not the case with the instantly claimed articles. The proteins of the claimed articles remain fully functional absent the labeling or printed instructions for use. It is further noted that the written material in the instructions is not considered to be within the statutory classes and does not carry patentable weight. See MPEP 706.03(a). Thus the instructions for use included in a kit or article manufacture constitute an “intended use” for that kit or article of manufacture. Intended use does not impart patentable weight to a product. See MPEP 2111.03 Intended use recitations and other types of functional language cannot be entirely disregarded. However, in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); *In re Otto*, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963). The intended use which is recited on the label or package insert lacks a function relationship to the compound because the insert or label does not

Art Unit: 1614

physically or chemically affect the chemical nature of the compound within the article of manufacture, and furthermore, the compound can still be used by the skilled artisan for other purposes. Therefore the compounds which are comprised within the article of manufacture are unpatentable over the prior art composition as combined, because they function equally effectively with or without the instructions, and accordingly no functional relationship exists between the instructions for use and the claimed composition. Thus the claims are addressed as being drawn to an article of manufacture comprising a chemical composition and a kit, the kit on the insert bearing no patentable weight.

Conclusion

No claim is found to be allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNA PAGONAKIS whose telephone number is (571)270-3505. The examiner can normally be reached on Monday thru Thursday, 9am to 5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number: 10/824,298

Page 15

Art Unit: 1614

AP

/Patricia A. Duffy/

Primary Examiner, Art Unit 1645